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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/641,721	08/15/2003	Deborah S. German	DEP798NP	2151
27777	7590	05/02/2006	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			COMSTOCK, DAVID C	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/641,721

Applicant(s)

GERMAN ET AL.

Examiner

David Comstock

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12, 13 and 15-18 is/are rejected.
- 7) ☒ Claim(s) 11 and 14 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 August 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/04, 4/04, 2/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Information Disclosure Statement

The Information Disclosure Statement filed 07 February 2005 refers to two sheets (see page 1, "Sheet 1 of 2"); however, there is no second sheet in the record. The I.D.S. has been considered as having only one sheet. If applicant intended for a second sheet to be considered, it should be submitted with the next response.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description:

- 28 (referring to the proximal surface of the prior art device shown in FIGS. 1-5; see the specification, page 3, lines 11-12).
- "line 14-14" is missing in FIG. 12 (see the specification, page 8, line 17, referring to "a cross-section taken along line 14-14 of FIG. 12."

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities:

- page 4, line 3, "FIG. 3" should be changed to --FIG. 5--, which shows the through-bore in cross-section as described.
- page 13, line 21, "would" should be changed to --is--.

Appropriate correction is required.

Claim Objections

Claim 18 is objected to because of the following informality: claim 18, line 1, "if" should be changed to --is--. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 7-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Howland (5,776,134).

Howland discloses an augment (i.e. a spacer) 150 comprising a first surface 156, a second surface 154, a thickness between the surfaces and a through-bore extending between the surfaces (see Fig. 15). The through-bore includes first and second identical countersinks 158, 159 having inner tapered surfaces and a smooth cylindrical

neck connecting the countersinks. The through-bore has a central longitudinal axis and a plane of symmetry perpendicular to the central longitudinal axis and between the sides (i.e., it is symmetrical as between the top and bottom portions thereof). The augment is reversible because it is symmetrical. The augment is a single-piece block with parallel sides.

Claims 1, 3-5, 12, 13 and 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Burkinshaw (6,214,052; cited by applicant).

Burkinshaw discloses a prosthetic implant and tibial device 10 comprising a tibial augment 72 mountable on a tibial component including a tray 12 and a stem 18 extending from a distal side of the tray (see Figs. 1 and 7; col. 1, lines 5-7; col. 2, lines 50-62; col. 3, lines 35-43; and col. 4, lines 28-51). The tibial tray has a plane of symmetry extending through the stem and a proximal side of the tray (i.e., it is symmetric as between its left and right sides). The tray includes a threaded bore 34 on each side of the plane of symmetry. The augment includes a through-bore that is smooth, i.e., non-threaded, from its first side to its second side, and includes a cylindrical surface defining a reduced diameter neck (in Fig. 1, see bores in augment 72a). The augment, e.g. 72a, is a block having parallel sides and is reversible by virtue of being able to be flipped over and used on either half (*N.B.* bore configuration and layout allow the wide bores to be used on one half and the narrow bores to be used on the other half with respect to the plane of symmetry through the stem and proximal side, cf., in Fig. 1, augments 72a and 72b).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burkinshaw (6,214,052; cited by applicant) in view of Kenna (4,944,760).

Burkinshaw discloses the claimed invention except for explicitly disclosing the components in a kit. Kenna discloses a method and instrumentation for knee revision surgery comprising a kit in order to provide the necessary components and facilitate the surgical procedure (see, e.g., title and claims 5 and 6). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the prosthetic implant and tibial device of Burkinshaw in a kit, in view of Kenna, in order to provide the necessary components and facilitate the surgical procedure.

Allowable Subject Matter

Claims 11 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: claims 11 and 14 both require at least a tibial component and a through-bore of a tibial augment having a central longitudinal axis and a plane of symmetry

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perpendicular to the central longitudinal axis. The latter is found in Howland (as set forth in the rejection under 35 USC 102(b) above) but a tibial component cannot be combined with the device of Howland (or vice versa) because Howland is not directed to analagous art. No other art of record anticipates or renders obvious claims 11 and 14.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



D. Comstock
27 January 2006